K120388

Section 5 -510(k) Summary

APR - 6 2012

1 Manufacturing Establishment and Contact Information

1.1 Manufacturer Name and Address:

Hologic, Inc.
35 Crosby Drive
Bedford, MA 01730

1.2 Establishment Registration Number:

1221300

1.3 Name, Title, and Telephone Number of Contact:

Name: Eileen M. Boyle
Title: Regulatory Affairs Specialist II
Phone: (781) 999-7781
Fax : (866) 652-8674
Email: eileen.boyle@hologic.com

2 Device Identification

2.1 Device Trade Name:

Hologic® InSight - FD Mini C-Arm Fluoroscopic Imaging System

2.2 Common/Usual Name

Fluoroscopic Imaging System

2.3 Proposed Intended Use:

The Fluoroscan InSight is a Mini C-Arm Fluoroscopic Imaging System designed to provide the physicians with general fluoroscopic visualization of a patient, including, but not limited to surgical orthopedic and podiatry use, critical and emergency care procedures, and light anatomy imaging situations.

3 Device Classification

3.1 Classification:

Class II

3.2 Classification Name and Rule

Image-Intensified Fluoroscopic X-Ray System, 21 CFR 892.1650

3.3 Classification Panel

Radiology

3.4 Product Code

OXO

3.5 Predicate Devices

- 510(k) No: K051754
  Trade Name: Orthoscan, OrthoScan HD
  (which includes OrthoScan HD with Flat Detector)
  SE Date: 8/9/2005
  Manufacturer: Orthoscan, Inc.

- 510(k) No: K113708
  Trade Name: Orthoscan Mobile DI
  SE Date: 1/5/2012
  Manufacturer: Orthoscan, Inc.

- 510(k) No: K051025
  Trade Name: Fluoroscan InSight Mini C-Arm Fluoroscopic Imaging System
  SE Date: 5/13/2005
  Manufacturer: Hologic, Inc.

4.0 Device Description

The Hologic® InSight-FD System , is a portable Mini C-Arm fluoroscopic imaging system with Flat Detector technology used by medical personnel in a variety of diagnostic, surgical and post-operative procedures for imaging extremities, including the hand, wrist, forearm, shoulder, foot, ankle and knee.

The hardware enhancements for the InSight-FD System exist primarily within the detector assembly and collimation. The InSight-FD System offers CMOS Flat Detector technology which provides a rectangular viewing area in comparison t the circular view with the conventional image intensifier. For user convenience, additional buttons were added to the X-ray source assembly control panel from the available functions.

The software enhancements for the InSight-FD System synchronize the rotation of the X-ray collimator with a manual rotation of +/-90 degrees. The synchronization enables the user to rotate the display image in a rectangular image as compared to the circular view of the image intensifier.

5 Performance Testing

Software verification and validation test was performed following the recommendations in the "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices." The purpose of the testing was to verify the incorporation and functionality of the flat panel detector on the Insight-FD System, that the accompanying software changes did not negatively impact the functionality, and that the functions and features tested meet their specific acceptance criteria.

Nonclinical and clinical information was provided following the recommendations in the "Guidance for the Submission of 510(k)s for Solid State X-ray Imaging Devices." This included information to characterize the solid state detector. Pairs of images were acquired to test the radiographic and fluoroscopic parameters (e.g., resolution, contrast detail, uniformity and motion) of the new Insight-FD with flat panel detector in comparison with the prior image intensified system.

Testing was also performed to demonstrate that the new Insight-FD with flat panel detector continues to comply with the applicable regulatory performance standards for radiation protection, including: 21 CFR 1020.30 (Diagnostic x-ray systems and their major components) and 21 CFR 1020.32 (Fluoroscopic equipment).

Testing was successfully conducted and demonstrated that the Hologic InSight-FD System meets all of its functional requirements and performance specifications.

6 Substantial Equivalence

The InSight-FD System is substantially equivalent to commercially available devices used for fluoroscopic imaging. The predicate devices selected for comparison are the OrthoScan- HD and the OrthoScan–HD with Flat Detector (K051754), OrthoScan Mobile DI (K113708) and the Fluoroscan InSight Mini C-Arm Fluoroscopic Imaging System (K051025). The predicate devices provide substantially equivalent or the same intended use, features and functions as the proposed device.

7 Conclusion

The features and functions on the InSight-FD System are substantially equivalent to those of the indicated commercially distributed devices: OrthoScan-HD with Flat Detector (K051754), OrthoScan Mobile DI (K113708) and Insight (K051025) with regard to intended use, performance, safety and effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

Ms. Eileen M. Boyle
Regulatory Affairs Specialist II
Hologic, Inc.
35 Crosby Drive
BEDFORD MA 01730

APR - 6 2012

Re: K120388
Trade/Device Name: InSight-FD Mini C-Arm Fluoroscopic Imaging System
Regulation Number: 21 CFR 892.1650
Regulation Name: Image-intensified fluoroscopic x-ray system
Regulatory Class: II
Product Code: OXO
Dated: March 12, 2012
Received: March 22, 2012

Dear Ms. Boyle:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely Yours,

Janine M. Morris
Acting Director
Division of Radiological Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

INDICATIONS FOR USE FORM

510(k) Number (if known): K120388

Device Name: **InSight - FD Mini C-Arm Fluoroscopic Imaging System**

Indications for Use:

The Fluoroscan InSight is a Mini C-Arm Fluoroscopic Imaging System designed to provide physicians with general fluoroscopic visualization of a patient, including, but not limited to surgical orthopedic and podiatry use, critical and emergency care procedures, and light anatomy imaging situations.

Prescription Use X (Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) K120388